

REMARKS

Applicants have now had an opportunity to carefully consider the Examiner's comments set forth in the Office Action of December 23, 2009.

Reconsideration of the Application is requested.

Claims 1, 3-4, and 6-17 are pending in the application.

Claims 2 and 5 are cancelled without prejudice.

Claims 1, 3, and 4 have been amended.

New claims 11-17 are added.

The Office Action

Claims 1-7 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Kadoma, et al. (JP 11180705, machine translation).

Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kadoma, et al., in view of Hall.

For the reasons outlined below, it is submitted that the application is in condition for allowance.

Claim 1 has been amended to incorporate claim 2 and now recites a method of producing a bone substitute material in the form of a block predominantly composed of carbonate apatite which includes forming carbonate apatite by contacting a block of calcium compound with a phosphate-containing solution. At least one of the calcium compound block and the phosphate solution contains a carbonate group. The calcium compound block is one prepared using an artificially synthesized calcium compound.

Such a method is not suggested by Kadoma, et al. Paragraph [0004] of the Kadoma reference, when manually translated, reads:

[Problem to be solved by the invention] An object of this invention is to provide the procedure of manufacturing, in a simple manner, without passing through a high temperature process, a solid substance which has a porous apatite at least on the surface thereof, for use as a material for adsorbing a biopolymer, an organic or inorganic ion harmful to a living body, a material for supporting a time-release drug, a material for

supporting a microorganism or an enzyme, etc.

In the method of Kadoma, a calcium content solid compound is contacted by a solution at a pH of 7 or more containing phosphoric acid ion. (¶[0005]). Natural materials, such as limestone, a shell, or coral, can be used as the starting material. (¶[0007], claims 5 and 6). None of these materials is prepared using an artificially synthesized calcium compound.

The Examiner points to Kadoma at ¶[0028], in which gypsum dihydrate is used as the starting material, which is calcium sulfate, not calcium carbonate. Thus, this material does not include a carbonate group.

The Examiner argues that the phosphate solution contains a carbonate group (a “calcium carbonate system”), referring to Kadoma, ¶[0015]. However, there is no reference to the solution containing carbonate in ¶[0015]. ¶[0016] of Kadoma does mention a “calcium carbonate system,” but this is in reference to the limestone and shell starting materials, rather than to the solution.

The equation at the end of paragraph [0006] does not include a carbonate group in either the starting material or solution. It is clear that carbonate apatite will never be formed via this equation.

Working examples 3 through 16, described ¶¶[0023- [0028] of Kardoma concern the production of a porous substance composed of other than carbonate apatite. ¶[0028] describes the production of the substances of Examples 5-16 via the equation shown in ¶[0006], thus not describing production of a bone substitute material composed of carbonate apatite.

Claim 1 also requires powders with a diameter of 20 micrometers or smaller are less than 1.0% by weight of the calcium compound block. The present inventors have discovered that the utilization of such a block of calcium compound containing substantially no powders can produce a bone substitute material having no histotoxicity without causing inflammatory reaction. (see ¶¶[0028] and [0029] of the present published application, US 2006/0225619). As noted in the present specification, the leading source of histotoxicity-causing inflammation in a bone prosthesis is impurities or antigenic substances contained in the starting calcium compound. In this respect, a preferred starting calcium material is an artificially synthesized calcium compound since

it is intrinsically low in impurities. By contrast, it has been previously proposed that carbonate apatite be produced through the fragmentation (pulverization) of naturally occurring calcium compounds.

The only calcium compounds for use as a starting material which may produce carbonate apatite that are suggested by Kadoma are all natural materials: limestone, shell, sea urchin shell and coral and in Working Examples 1 and 2 ([0019] - [0022] of Kadoma), the limestone and shell are pulverized. As will be appreciated, such naturally occurring materials cannot produce a bone substitute material which does not cause inflammation due to histotoxicity, because they inherently contain natural impurities in addition to powders having a diameter of 20 μ m. The other starting materials in Kadoma, including those employed in Working examples 3-16, will never produce a carbonate apatite.

Further, one of ordinary skill in the art would have seen no reason to use artificially synthesized calcium compound in Kadoma's method. Kadoma does not aim to produce a bone substitute material but only a substance for use as adsorbents or carriers. Thus, the question of inflammation due to histotoxicity, is not of concern to Kadoma.

Regarding claim 8, the Hall reference discloses a pore size for bone implants made of metal alloy, but does not teach one of ordinary skill how to achieve this using, for example, Kadoma's hydrated hardened body of gypsum fibrosum. Further, since Kadoma is not directed to a bone implant, it would not have been obvious to try to achieve the pore sizes suggested by Hall.

Accordingly, it is submitted that claim 1 and claims 3, 7, 8, and 11-16 dependent therefrom distinguish over the references of record.

Claim 4 recites a bone substitute material produced by a method comprising forming carbonate apatite by contacting a block of calcium compound with a phosphate-containing solution, wherein the calcium compound block contains substantially no powders such that powders with a diameter of 20 micrometers or smaller are less than 1.0% by weight, and wherein the block of calcium compound is one prepared using an artificially synthesized calcium compound.

The material produced by Kadoma's method produces a material which is very

different to that claimed. It is not a bone substitute material and, even if produced with natural calcium carbonate materials, the powder present by pulverization of these materials and the inherent contaminants will result in a material which would cause inflammation due to histotoxicity. Further, as shown in Example 1 of the present specification, when calcium sulfate is used without a carbonate group present, an inferior product is produced.

Dependent claim 6 recites that the artificially synthesized calcium compound is a foamed calcium compound. The porous substance of Kadoma is said to have a pore size in the order of several micrometers, which would not be expected to produce a bone substitute material.

Accordingly, it is submitted that claim 4 and claim 6 dependent therefrom distinguish over Kadoma.

Claim 9 recites a method of producing a bone substitute material predominantly composed of carbonate apatite which includes providing a porous body formed of a calcium compound, the body containing substantially no powders and having an average pore diameter in a range of 50-1000 μ m, contacting the porous body with a phosphate-containing solution, at least one of said porous body and said phosphate solution containing a carbonate group, whereby the porous body is predominantly composed of carbonate apatite.

Kadoma does not suggest a porous body formed of a calcium having an average pore diameter in a range of 50-1000 μ m. The Hall reference discloses a pore size for bone implants made of metal alloy, but does not teach one of ordinary skill how to achieve this using, for example, Kadoma's hydrated hardened body of gypsum fibrosum. Further, since Kadoma is not directed to a bone implant, it would not have been obvious to try to achieve the pore sizes suggested by Hall in the material of Kadoma.

Accordingly, it is submitted that claims 9 and 17 distinguish over the references of record.

CONCLUSION

For the reasons detailed above, it is respectfully submitted all claims remaining in the application (Claims 1, 3-4, and 6-17) are now in condition for allowance.

☒ Remaining Claims, as delineated below:

(1) FOR	(2) CLAIMS REMAINING AFTER AMENDMENT LESS HIGHEST NUMBER PREVIOUSLY PAID FOR		(3) NUMBER EXTRA
TOTAL CLAIMS	15	- 20 =	0
INDEPENDENT CLAIMS	3	- 3 =	0

Respectfully submitted,

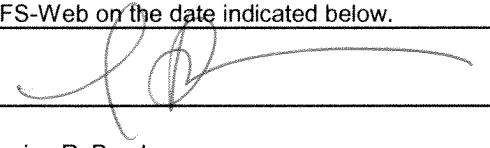
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